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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,891	07/17/2003	Graham Alan March	GAM 6410.1	2751
321	7590	02/20/2009	EXAMINER	
SENNIGER POWERS LLP 100 NORTH BROADWAY 17TH FLOOR ST LOUIS, MO 63102			KANTAMNENI, SHOBHA	
			ART UNIT	PAPER NUMBER
			1617	
			NOTIFICATION DATE	DELIVERY MODE
			02/20/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspatents@senniger.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/622,891	<b>Applicant(s)</b> MARCH, GRAHAM ALAN	
	<b>Examiner</b> Shobha Kantamneni	<b>Art Unit</b> 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,3,6-15,18-26,29-32 and 64-76 is/are pending in the application.
- 4a) Of the above claim(s) 64-76 is/are withdrawn from consideration.
- 5) ☒ Claim(s) NONE is/are allowed.
- 6) ☒ Claim(s) 2,3,6,7-15,18-26,29-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

This office action is in response to applicant's response filed on 11/17/2008.

Applicant's amendment filed on 11/17/2008, wherein claims 2, 3, 6, 7, 20, 22 have been amended, and claims 1, and 63 have been canceled. Amendment also added new claims 64-76.

Claims 2, 3, 6-15, 18-26, 29-32, 64-76 are pending.

Newly submitted claims 64-76 are directed to an invention that is independent or distinct from the invention originally elected. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 64-76 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's arguments have been considered, but not found persuasive. The rejection of claims 1-3, 6, 10, and 63 under 35 U.S.C. 103(a) as being unpatentable over Samid et al. (6,037,376, PTO-892), in view of Rubenstein et al. (US 2002/0115619, PTO-892), and further in view of D'Silva (US 6,550,955, PTO-892) is MAINTAINED. See under response to arguments.

Applicant's arguments have been considered, but not found persuasive. The rejection of claims 1-3, 6-15, 18-26, 29-32, and 63 under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (US 2002/0115619, PTO-892), in

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view of D'Silva (US 6,550,955, PTO-892) is MAINTAINED. See under response to arguments.

Claims 2-3, 6-15, 18-26, 29-32, are examined herein on the merits.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3, 6, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samid et al. (6,037,376, PTO-892), in view of Rubenstein et al. (US 2002/0115619, PTO-892), and further in view of D'Silva (US 6,550,955, PTO-892).

Samid et al. discloses pharmaceutical compositions comprising sodium phenylbutyrate, a water soluble sweetening agent, sugar, and a binder, Sterotex. See column 25-26, EXAMPLE 18, EXAMPLE 21, and EXAMPLE 21.

Samid et al. do not explicitly teach an aromatic flavoring agent.

Samid et al. do not teach the employment of the particular synthetic sweetening agents aspartame and potassium acesulfame.

Rubenstein et al. (US 2002/0115619, PTO-892) teach that sodium 4-phenylbutyrate has bad taste in the mouth. See page 13, paragraph [0143]. Rubenstein et al. teaches that compositions in the form of Tablet therein can

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contain sweetening agent, a flavoring agent, or some combinations thereof in order to provide pharmaceutically elegant and palatable preparation. See page 8, paragraphs [0097]-[0105]; paragraph [0112].

D'Silva teaches that many medicinal compounds possess unpleasant taste characteristics. D'Silva further teaches that flavors and sweeteners are added to the medicinal compounds to enhance the palatability of the product. See column 6, lines 41-67; column 7, lines 1-9. It is disclosed that sweeteners such as aspartame, acesulfame potassium, saccharin, sucralose or mixtures, and fruit flavors such as cherry, grape, orange, strawberry or lemon are employed. See column 6, lines 41-67; column 7, lines 1-9. It is also taught that the amount of sweetener used in the pharmaceutical composition therein can be from about 0.01 % w/v to about 5.0 % w/v. The flavoring agent can be present in an amount up to 5 grams per 100 mL of the suspension. See line 55-column 4, line 6, column 5; column 10, claims 1, 4.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ aromatic flavoring agents, and specific synthetic sweetening agents aspartame and potassium acesulfame in the compositions comprising sodium 4-phenylbutyrate taught by Samid et al. because 1) Rubenstein et al. teach that sodium 4-phenylbutyrate has a bad taste, and also teaches that the compositions comprising sodium 4-phenylbutyrate can contain flavoring agents, and artificial sweetening agents, and 2) D'Silva teaches that aspartame, acesulfame potassium, saccharin, sucralose, and fruit flavors such as cherry, grape, orange, strawberry or lemon are employed in pharmaceutical

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compositions to mask the disagreeable taste of the pharmaceutically active agent. Thus, one of ordinary skill in the art at the time of invention would have been motivated to employ the well known fruit flavoring agent, strawberry flavoring agent, and the well artificial sweeteners with reasonable expectation of obtaining a pharmaceutical composition that is palatable, and masks the disagreeable taste of sodium 4-phenylbutyrate.

Furthermore, as the combined teachings of Samid et al., Rubenstein et al., D,Silva renders the claimed pharmaceutical composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate in independent claim 10 are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

### ***Response to Arguments***

Applicant argues that "Samid discloses in Examples 18 and 21, pharmaceutical compositions which comprise sodium 4-phenylbutyrate. Example 18 relates to a tablet formulation. In general, since tablets can be taken quickly by an adult, the taste and odor issues are not as problematic as they are in formulating something that will be taken as a liquid by a child. Thus the

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formulation of Example 18, whilst indicating that sodium 4-phenylbutyrate may be used in a pharmaceutical does not give any suggestion that it can be provided to a small child in liquid form." These arguments have been considered, but not found persuasive. It is pointed out that Samid need not teach that sodium 4-phenylbutyrate can be provided to a small child in liquid form, since the claims are drawn to a pharmaceutical composition, and not to a method of administering to a small child.

Applicant argues that "Although Rubenstein discloses that sodium 4-phenylbutyrate causes a bad taste in the mouth, he does not teach or suggest that the particular combination of sweeteners and flavorant as claimed will mask the pungent rodent-like odor of sodium 4-phenylbutyrate." These arguments have been considered, but not found persuasive. Rubenstein et al. teach that sodium 4-phenylbutyrate has bad taste in the mouth. Rubenstein et al. teaches that compositions in the form of Tablet therein can contain sweetening agent, a flavoring agent, or some combinations thereof in order to provide pharmaceutically elegant and palatable preparation. Samid et al. discloses pharmaceutical compositions comprising sodium phenylbutyrate, a water soluble sweetening agent, sugar, and a binder, Sterotex. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to employ the well known fruit flavoring agent, strawberry flavoring agent, and the well artificial sweeteners taught by D'Silva with reasonable expectation of obtaining a pharmaceutical composition that is palatable, and masks the disagreeable taste of sodium 4-phenylbutyrate.

Applicant argues that "D'Silva's general teaching of the use of sweeteners and flavorants to mask unpleasant taste of a pharmaceutical also fails to recognize the odor problem associated specifically with sodium 4-phenylbutyrate." These arguments have been considered, but not found persuasive because applicant is arguing against a single reference when the rejection was based on combination of references. It is pointed out D'Silva reference was employed for its teachings that many medicinal compounds possess unpleasant taste characteristics, and fruit flavors such as cherry, grape, orange, strawberry or lemon, and sweeteners such as aspartame, acesulfame potassium, saccharin, sucralose or mixtures are added to the medicinal compounds to enhance the palatability of the product. Samid et al. discloses pharmaceutical compositions comprising sodium phenylbutyrate, a water soluble sweetening agent, sugar, and a binder, Sterotex. Rubenstein et al. teach that sodium 4-phenylbutyrate has bad taste in the mouth. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to employ the well known fruit flavoring agent, strawberry flavoring agent, and the well artificial sweeteners taught by D'Silva with reasonable expectation of obtaining a pharmaceutical composition that is palatable, and masks the disagreeable taste of sodium 4-phenylbutyrate.

Applicant argues that "At the time of the invention, there were a multiplicity of sweeteners and flavors to choose from with the goal of possibly masking the disagreeable taste of sodium 4- phenylbutyrate." These arguments have been considered, but not found persuasive as discussed above.



Applicant argues that “Inherency cannot be established by probabilities or possibilities and there is no evidence of record that the masking of odor by the claimed composition would have necessarily and inevitably resulted from the selection of flavoring agents and a mixture of aspartame and potassium acesulfame in a composition comprising sodium 4-phenylbutyrate. Nor is such masking of odor recognized in the art, particularly given that none of the cited references address the odor problem.” These arguments have been considered, but not found persuasive. Rubenstein et al. clearly teach that sodium 4-phenylbutyrate has bad taste in the mouth. Rubenstein et al. also teach that to provide pharmaceutically elegant and palatable preparation compositions can contain sweetening agent, a flavoring agent, or some combinations thereof. D’Silva teaches that many medicinal compounds possess unpleasant taste characteristics. D’Silva further teaches that flavors and sweeteners are added to the medicinal compounds to enhance the palatability of the product. Accordingly as discussed above, the combined teachings of Samid et al., Rubenstein et al., D’Silva renders the claimed pharmaceutical composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate in independent claim 10 are inseparable from its composition. Therefore, if the prior art renders the composition obvious, then the properties are also rendered obvious by the prior art.

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Applicant argues that "The Office has not cited any evidence of the use of sweeteners and flavorants in amounts sufficient to mask the pungent rodent-like odor of sodium 4-phenylbutyrate." These arguments have been considered, but not found persuasive. It is pointed out that claim 10, does not recite any particular amounts of sweeteners and flavorants to mask the pungent odor. As the combined teachings of Samid et al., Rubenstein et al., D,Silva renders the claimed pharmaceutical composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate in independent claim 10 are inseparable from its composition. Therefore, if the prior art renders the composition obvious, then the properties are also rendered obvious by the prior art.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-3, 6-15, 18-26, 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubenstein et al. (US 2002/0115619, PTO-892), in view of D'Silva (US 6,550,955, PTO-892).

Rubenstein et al. discloses a pharmaceutical composition comprising sodium 4-phenylbutyrate. See page 2, paragraph [0019], [0022]; page 11, [0122]; page 13, [0143]. It is also taught that the pharmaceutical compositions therein can be in the form of a tablet, a soft capsule, a chachet, a troche, or a lozenge. The formulations for oral administration include, a powdered or granular formulation, an aqueous or oily suspension, an aqueous or oily solution or emulsion. The compositions therein can contain binding agents such as polyvinylpyrrolidone, hydroxypropyl methylcellulose. The compositions comprise from 0.1 % to 100 % (w/w) active ingredient. Page 8, paragraph [0094]. It is also disclosed that sodium 4-phenylbutyrate has bad taste in the mouth. See page 13, paragraph [0143]. The compositions in the form of Tablet therein can contain sweetening agent, a flavoring agent, or some combinations thereof in order to provide pharmaceutically elegant and palatable preparation. Sweetening agents include glycerol, propylene glycol, sorbitol, sucrose, and saccharin i.e a synthetic sweetening agent. See page 8, paragraphs [0097]-[0105]; paragraph [0112]. It is also taught that the pharmaceutical compositions therein can be in a single or multi unit-dose. See page 8, paragraph [0090].

Rubenstein et al. do not explicitly teach an aromatic flavoring agent.

Rubenstein et al. do not teach the employment of the particular synthetic sweetening agents aspartame and potassium acesulfame.

Rubenstein does not specifically teach the particular amounts of flavoring agents, sweetening agents, and binding agent in the composition therein.

D'Silva teaches that many medicinal compounds possess unpleasant taste characteristics. D'Silva further teaches that flavors and sweeteners are added to the medicinal compounds to enhance the palatability of the product. taste masked pharmaceutical compositions. See column 6, lines 41-67; column 7, lines 1-9. It is disclosed that sweeteners such as aspartame, acesulfame potassium, saccharin, sucralose or mixtures, and fruit flavors such as cherry, grape, orange, strawberry or lemon are employed. See column 6, lines 41-67; column 7, lines 1-9. It is also taught that the amount of sweetener used in the pharmaceutical composition therein can be from about 0.01 % w/v to about 5.0 % w/v. The flavoring agent can be present in an amount from about 0.05 % to about 2.0 % by weight. of the composition. See line 55-column 4, line 6, column 5; column 10, claims 1, 4.

It would have been obvious to a person of ordinary skill in the art at the time of invention to employ aromatic flavoring agents, and specific synthetic sweetening agents aspartame and potassium acesulfame in the compositions comprising sodium 4-phenylbutyrate because 1) Rubenstein et al. teach that sodium 4-phenylbutyrate has a bad taste, and also teaches that the compositions comprising sodium 4-phenylbutyrate can contain flavoring agents, and artificial sweetening agents, and 2) D'Silva teach that aspartame, acesulfame potassium,

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saccharin, sucralose in amount from about 0.01 % w/v to about 5.0 % w/v of composition, and fruit flavors such as cherry, grape, orange, strawberry or lemon in an amount from about 0.05 % to about 2.0 % by weight. of the composition are employed in pharmaceutical compositions to mask the disagreeable taste of the pharmaceutically active agent . Thus, one of ordinary skill in the art at the time of invention would have been motivated to employ the well known fruit flavoring agent, strawberry flavoring agent, and the well artificial sweeteners with reasonable expectation of obtaining a pharmaceutical composition that is palatable, and masks the disagreeable taste of sodium 4-phenylbutyrate.

It would have been obvious to a person of ordinary skill in the art at the time of invention to determine or optimize parameters such as amounts of flavoring agents, sweetening agents, and binding agent employed in the composition of Rubenstein et al., to obtain a pharmaceutical composition.

One having ordinary skill in the art at the time the invention was made would have been motivated to determine the amounts of flavoring agents, sweetening agents, and binding agent employed in the compositions, since D'Silva teach such amounts of flavoring agents, sweetening agents, and further the optimization of amounts of known agents in a composition, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art.

It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Furthermore, as the combined teachings of Rubenstein et al., D'Silva renders the claimed pharmaceutical composition obvious, the property of such a claimed composition will also be rendered obvious by the prior art teachings, since the properties, namely to mask substantially the bitter taste and pungent odor of sodium 4-phenylbutyrate in independent claims 10, 13, 20, 22 are inseparable from its composition. Therefore, if the prior art teaches the composition or renders the composition obvious, then the properties are also taught or rendered obvious by the prior art. In re Spada, 911 F.2d 705, 709, 15 USPQ 1655, 1658 (Fed. Cir. 1990.) See MPEP 2112.01. The burden is shifted to Applicant to show that the prior art product does not possess or render obvious the same properties as the instantly claimed product.

It is pointed out that the recitation “the unit dose prepared by diluting with water an aliquot of a concentrated aqueous solution containing at least about 200 mg/ml of sodium 4-phenylbutyrate” in instant claim 20, and “wherein the granules are mixed with the at least one synthetic water soluble softening agent and with at least one water soluble flavoring agent to form the wetted mass” in claim 31, are product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 ('Fed. Cir. 1985). See MPEP 21 13.

***Response to Arguments***

Applicant argues that “The Rubenstein reference regarding sodium 4-phenylbutyrate does not suggest dosage forms as claimed, but rather only describe tablets, a dosage form which cannot be taken by children.” These arguments have been considered, but not found persuasive. It is pointed out that contrary to applicant’s arguments, Rubenstein teaches that formulation for oral administration can be in the form of powdered or granular formulation, and meets instant claim 10 limitation.

Regarding Applicant’s arguments that the masking of odor is not recognized in the art, and none of the cited references address the odor problem, it is pointed out again that 1) Rubenstein teaches that sodium 4-phenylbutyrate has bad taste in the mouth i.e Rubenstein recognizes the unpleasant taste of sodium 4-phenylbutyrate, and 2) D’Silva teaches that many medicinal compounds possess unpleasant taste, and flavors and sweeteners are added to enhance the palatability of the medicinal compounds. Accordingly, one of ordinary skill in the art at the time of invention would have been motivated to employ the well known fruit flavoring agent, strawberry flavoring agent, and the well known artificial sweeteners with reasonable expectation of obtaining a pharmaceutical composition that is palatable, and masks the disagreeable taste of sodium 4-phenylbutyrate. One having ordinary skill in the art at the time the invention was made would have been motivated to determine the amounts of flavoring agents, sweetening agents, and binding agent employed in the compositions, since D’Silva teach such amounts of flavoring agents, sweetening

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agents, and further the optimization of amounts of known agents in a composition, is considered well in the competence level of an ordinary skilled artisan in pharmaceutical science, involving merely routine skill in the art. It has been held that it is within the skill in the art to select optimal parameters, such as amounts of ingredients, in a composition in order to achieve a beneficial effect such to mask the bad taste of 4-phenylbutyrate. See *In re Boesch*, 205 USPQ 215 (CCPA 1980).

Applicant's arguments with respect to unexpected results have been fully considered but are not deemed persuasive as to the nonobviousness and/or unexpected results of the claimed invention over the prior art. Applicant's data provide no clear and convincing evidence of nonobviousness or unexpected results over the cited prior art because Applicant merely provides one particular composition, with one particular amounts of ingredients, see page 20, EXAMPLE 1. Thus, the evidence is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the compounds in the claimed composition. See MPEP 716.02. Therefore, the evidence presented in specification herein is not seen to be clear and convincing in support the nonobviousness of the instant claimed invention over prior art.

### ***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period, will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-friday, 8am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, Ph.D can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shobha Kantamneni, Ph.D

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Patent Examiner

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/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617